

## REMARKS

The Office Action has maintained the restriction requirement earlier imposed, and has restricted the subject matter to A is CH=CH- and G is G<sup>1</sup> or G<sup>2</sup>. In addition, it has withdrawn claims 73-77 from further consideration. The Office Action also requested that a Supplemental IDS be filed to complete the citations presented in an earlier IDS. The Office Action has rejected Claim 57 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Further Claims 55-57, 60 and 72, and claims dependent thereon are rejected under 35 U.S.C. §102(a) and (e), as allegedly being anticipated by the teachings in WO 9,813,411 (or its U.S. equivalent, U.S. Patent No. 5,925,527), in which Hayes, et al. are listed as inventors. ("Hayes et al."). In addition, Claims 55-71 have been rejected on the grounds of non-statutory obviousness-type double patenting as allegedly being unpatentable over Claims 8-20 of U.S. Patent No. 6,509,572. The Office Action also brings to applicants' attention, U.S. Patent No. 6,313,153, where the Office Action alleges that it claims subject matter that is similar and/or identical to that claimed herein.

At the outset, before addressing the merits of the Office Action, the applicants wish to thank Examiner Coleman for the courtesy extended to applicants' representative during the telephone interview conducted on August 8, 2006, and for the helpful suggestions for advancing the prosecution of the present application.

In accordance with the restriction requirement, applicants have, without prejudice, deleted from claims 55-60 and 70-72 the non-elected subject matter. Further, in accordance with the restriction requirement, applicants have canceled claims 73-77 without prejudice. However, it is to be noted that applicants have not abandoned the subject matter deleted from the instant application, and reserve the right to file a divisional application directed to the deleted subject matter.

Further, since  $R_7$  was defined in terms of  $R_6$  and since, as a result of the restriction requirements,  $R_6$  was deleted from the claims, applicants have specifically recited the definition of  $R_7$  in claims 55-60 and 70-72. In claims 55-57, 60 and 72, the definition of D has been amended to recite that when D is an alkylene, with the exception of the (G) terminal methylene group in the  $C_3 - C_{12}$  alkylene, one to three methylene units in the  $C_3 - C_{12}$  alkylene may be isosterically replaced by O, S, CO, SO or  $SO_2$ . Support thereof is found in the original definition of D, described on Page 19 of the instant specification. Finally, Claim 57 has been amended to correct a typographical error by deleting the ultimate "and" therein. Further, Claims 55, 60 and 72 have deleted the provisos recited therein as they are superfluous in view of the amendments to the definitions of A and D. Further, Claim 60 has been amended to delete the redundancy of the definition of  $R^{10}$ .

No new matter has been added to the application.

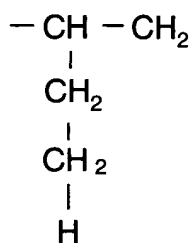
Applicants are enclosing herewith a Supplemental Disclosure statement that lists and identifies those items that were not previously identified in the IDS dated December 28, 2000. It is to be noted that one of the references, a publication by Eder, et al. in "Allgemeine Pathologie und Pathologische Anatomie", Springer-Verlag, Berlin, 33<sup>rd</sup> Ed., 208-213 1990, is in the German language. Applicants have translated into English the relevant portions thereof, which are also submitted herewith.

The Office Action has rejected Claim 57 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action has alleged that the definition of the substituents on the aromatic ring systems of  $R^7$ ,  $R^8$ ,  $R^9$ ,  $R^{10}$ ,  $R^{11}$ ,  $R^{12}$ ,  $Ar^1$ ,  $Ar^2$  and  $=CR^8R^9$  where the substituent is for two adjacent residues on the aromatic ring is not defined in the specification with respect to the genus when it is anything other than methylenedioxy. Applicants concur. Claim 57 has been amended to be consistent therewith by

deleting the "and" in the last line of the claim. By so amending the claim, the claim is now consistent with the definition in the specification.

This amendment overcomes the rejection of Claim 57 under 35 U.S.C. §112, first paragraph. Withdrawal thereof is respectfully requested.

Pursuant to the rejection of Claims 55-57, 60 and 72 under 35 U.S.C. §102(a) and (e), the Office Action cites Hayes, et al. According to the Office Action, Hayes et al. disclose the compounds of the present invention, where R<sup>1</sup> is H, R<sup>2</sup> is H, R<sup>3</sup> is H, A is CH-CH<sub>2</sub>, D is -CH (CON H<sub>2</sub>)-CH<sub>2</sub> and G is 4-nitrophenyl. According to the Office Action, D is C<sub>4</sub>-alkylene, i.e.,



The Office Action alleges that when two of the methylene groups of D are replaced by NH and CO, then the product is (CH) - (CO NH<sub>2</sub>)-CH<sub>2</sub>-H, which is the end product as allegedly taught by Hayes et al.

It is apparent that this reference is only relevant when D is an alkylene group. If, however, D is alkylene, and the methylene groups therein is not isosterically replaced by NR<sup>7</sup>, then the end product cannot contain an amide, i.e., it cannot be -CH (CO NH<sub>2</sub>)-CH<sub>3</sub>-.

The subject matter in claims 55-57, 60 and 72 do not permit the methylene groups of the alkylene group to be replaced by an amino group since, as defined, one to three methylene groups, are only isosterically replaced by O, S, CO, SO or SO<sub>2</sub>. Thus, as amended, the methylene unit of the alkylene group of D cannot be replaced isosterically with NR<sup>7</sup>. Thus, one to three methylene units in the alkylene moiety in the definition of D cannot be replaced by CO

N H. Accordingly, Hayes, et al. do not anticipate the present invention. The rejection of Claims 55-57, 60 and 72 has been overcome. Withdrawal thereof is respectfully requested.

Pursuant to the obviousness double patenting, the Office Action cites U.S. Patent No. 6,506,572 which has been assigned to Klinge Pharma GmbH. The present application has been assigned by the inventors to Klinge Pharma GmbH. However, Klinge Pharma GmbH changed its name on January 2, 2002 to Fujisawa Deutschland GmbH, which, in turn, merged with another company to become Fujisawa GmbH which changed its name to Astellas Pharma GmbH. Thus the present application is owned by Astellas Pharma GmbH, as evidenced by the Merger and Change of Name forms which were filed with the USPTO on July 17, 2006, and recorded at Reel 009932/0544, 018109/0863, 018120/0097, 018109/0084, 018109/0917, 018120/0102 and 018120/0108. In view of the activity described hereinabove, the '572 patent is also owned by Astellas Pharma GmbH although there does not appear to be any document filed to date in the USPTO Recording Office to that effect.

Applicants are filing herewith a terminal disclaimer. The submission of the terminal disclaimer obviates the obviousness double patenting rejection. Withdrawal thereof is respectfully requested.

The Office Action has brought to the attention of applicant U.S. Patent No. 6,313,153 ("153 patent"). It contains several independent claims, viz., claims 1, 4, 5, 8, 9, 10, 11, 12, 13, and 14. Claims 1, 4, 5, 8, 9, 10, 11, 12 and 13 recite the use of the compounds thereon for treating nephritis, inhibiting TG F-B, treating a patient with liver cirrhosis, treating a fibrosis, treating chronic renal insufficiency, treating pulmonary fibrosis, treating a diabetic nephropathy and treating a retinopathy, respectively.

The only claims pending in the above identified application which are method claims are claims 70, 71, and 72, which are directed to a method of inhibiting tumor cell growth in a human

or animal body, a method of suppressing autoimmune disease in a human or animal body and a process of making the compounds claimed herein, respectively.

The '153 patent does not claim a process of making the compound therein, so that the subject matter of claim 72 of the present application does not claim identical or similar subject matter reciting the '153 patent. Further, a method of suppressing autoimmune disease and a method of inhibiting tumor cell growth, as recited in claims 71 and 70 of the instant specification, is not directed to identical or similar subject matter to a method of treating retinopathy, diabetic nephropathy, pulmonary fibrosis, chronic renal insufficiency, fibrosis, liver cirrhosis, or nephritis, as recited in claims 14, 13, 12, 11, 10, 9, 8 and 1 (and dependent claims 2-3, respectively of the '153 patent). Thus, claims 70 and 71 do not claim identical or similar subject matter to that recited in claims 1-3, and 8-13. Claims 4-5 of the '153 patent are directed to a method for inhibiting a TGF-B and treating a patient with a TGF-B involving disease, respectively. Attention is directed to Column 1, line 31-37 of the '153 patent, which lists various diseases associated with TGF-B. It is to be "noted that "tumors and autoimmune diseases", the subject matter of claims 70 and 71 of the instant application are not listed in the aforementioned passage in the '153 patent. Thus, claims 70 and 71 of the present application does not claim identical or similar subject matter to that of claims 4 or 5. Claims 6 and 7, of the '153 patent are dependent on claims 1 or 5. Since neither claim 1 nor claim 5 claim the same or similar subject matter to claims 70 or 71 of the present application, then claims 6 or 7 do not claim the same or similar subject matter to the present application.

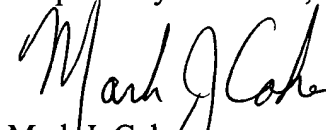
Claims 55-69 of the present application claim *inter alia*, 3-pyridyl derivatives. On the other hand, claims 14-16 of the '153 patent claim pyridyl acrylamide compounds where Ar is pyridyl, but excludes 3-pyridyl compounds. The claims specifically state that Ar<sup>1</sup> is not a 3-

pyridyl group. Thus, the subject matter claims 55-69 of the present application do not overlap with or interfere with the subject matter of claims 14-16 of the '153 patent.

Thus, it is applicants' position that the subject matter of the present application does not interfere with the subject matter of the '153 patent.

In view of the amendment to the claims and the remarks herein, it is respectfully submitted that the present application is in condition of allowance, which action is earnestly solicited.

Respectfully submitted,

  
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Attachment – Terminal Disclaimer with check for \$130.00